IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDA PHARMACEUTICALS INC. and CIPLA LTD., *Plaintiffs*, v. PERRIGO UK FINCO LIMITED PARTNERSHIP, PERRIGO COMPANY, and PERRIGO PHARMACEUTICALS CO. *Defendants*.	)	Civil Action No. _______________

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Meda Pharmaceuticals Inc. ("Meda") and Cipla Ltd. ("Cipla") (collectively, "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, against defendants Perrigo UK Finco Limited Partnership ("Perrigo UK"), Perrigo Company ("Perrigo Co."), and Perrigo Pharmaceuticals Company ("Perrigo Pharmaceuticals") (collectively, "Perrigo"). Perrigo filed or caused to be filed Abbreviated New Drug Application ("ANDA") No. 208111 with the U.S. Food and Drug Administration ("FDA"). ANDA No. 208111 ("Perrigo ANDA") seeks approval to market a 137 mcg strength azelastine hydrochloride and 50 mcg strength fluticasone propionate combination nasal spray ("Generic Product")—a generic version of Plaintiff Meda's proprietary DYMISTA® drug product—before expiration of Plaintiff Cipla's U.S. Patent Nos. 8,168,620 ("the '620 patent") and 9,259,428 ("the '428 patent") all of which cover the DYMISTA® drug product, and for each of which Plaintiff Meda is the exclusive licensee in the United States.

PARTIES

2. Meda is a corporation organized and existing under the laws of Delaware, and having its principal place of business at 265 Davidson Avenue, Suite 300, Somerset, New Jersey 08873-4120.

3. Cipla is a publicly held company organized and existing under the laws of India, and having a registered office at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400 013, Maharashtra, India.

4. On information and belief, Perrigo UK is a limited partnership organized and existing under the laws of the United Kingdom, with its principal place of business at Wrafton, Braunton, Devon, EX33 2DL, United Kingdom.

5. On information and belief, Perrigo Co. is a corporation organized and existing under the laws of the State of Michigan, with its principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010.

6. On information and belief, Perrigo Pharmaceuticals is a corporation organized and existing under the laws of the State of Michigan, with its principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010.

7. On information and belief, Perrigo UK and Perrigo Co. are affiliates of each other and are both subsidiaries of Perrigo Company plc.

8. On information and belief, Perrigo Pharmaceuticals is a wholly-owned subsidiary of Perrigo Co. and functions as a fully-integrated entity.

9. On information and belief, Perrigo UK, Perrigo Co., and Perrigo Pharmaceuticals act as agents of each other and work together to, *inter alia*, develop, manufacture, obtain

regulatory approval, market, sell, and distribute generic copies of branded pharmaceutical products throughout the United States, including within this Judicial District.

10. On information and belief, Perrigo Co., with its subsidiary Perrigo Pharmaceuticals, acts as Perrigo UK's U.S. agent, including, at least, with respect to the Perrigo ANDA and the Paragraph IV notices associated with the Perrigo ANDA.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

12. This Court has personal jurisdiction over Perrigo UK. On information and belief, Perrigo UK develops and manufactures pharmaceutical products for the United States market and derives substantial revenue from the sale of such products to customers in Delaware.

13. On information and belief, Perrigo UK, directly or in concert with related companies including Perrigo Co. and Perrigo Pharmaceuticals, is doing business in Delaware, including in this Judicial District by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware.

14. Upon information and belief, Perrigo UK, directly or in concert with related companies including Perrigo Co. and Perrigo Pharmaceuticals, has engaged in substantial and/or continuous and systematic contacts with Delaware which satisfy due process and confer personal jurisdiction over Perrigo UK in Delaware.

15. Further, Perrigo UK has committed, or aided, abetted, contributed to and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm

and injury to Meda and Cipla, which manufactures DYMISTA® for sale and use throughout the United States, including in this Judicial District. In addition, on information and belief, if Perrigo's ANDA received approval, Perrigo UK would market and sell generic versions of DYMISTA® in Delaware.

16. Perrigo UK has also been sued in this Judicial District and has previously consented to personal jurisdiction. *See, e.g.*, *LEO Pharma A/S et al v. Perrigo UK Finco Limited Partnership and Perrigo Company*, No. 16-cv-00430 (D. Del.) and *Taro Pharmaceuticals USA, Inc. et. al. v. Perrigo UK Finco Limited Partnership*, No. 15-cv-00859 (D. Del.).

17. This Court also has personal jurisdiction over Perrigo Co. On information and belief, Perrigo Co. develops and manufactures pharmaceutical products for the United States market and derives substantial revenue from the sale of such products to customers in Delaware.

18. On information and belief, Perrigo Co., directly or in concert with related companies including Perrigo UK and Perrigo Pharmaceuticals, is doing business in Delaware, including in this Judicial District by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware.

19. Upon information and belief, Perrigo Co., directly or in concert with related companies including Perrigo UK and Perrigo Pharmaceuticals, has engaged in substantial and/or continuous and systematic contacts with Delaware which satisfy due process and confer personal jurisdiction over Perrigo Co. in Delaware.

20. Further, Perrigo Co. has committed, or aided, abetted, contributed to and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Meda and Cipla, which manufactures DYMISTA® for sale and use throughout the

United States, including in this Judicial District. In addition, on information and belief, if Perrigo's ANDA received approval, Perrigo Co. would market and sell generic versions of DYMISTA® in Delaware.

21. Perrigo Co. has also been sued in this Judicial District and has previously consented to personal jurisdiction. *See, e.g.*, *LEO Pharma A/S et al v. Perrigo UK Finco Limited Partnership and Perrigo Company*, No. 16-cv-00430 (D. Del.) and *Endo Pharmaceuticals Solutions Inc.,et al v. Paddock Laboratories, LLC and Perrigo Company,* No. 14-cv-1422 (D. Del.).

22. Further, this Court has personal jurisdiction over Perrigo Pharmaceuticals. Pursuant to 24 Del. C. § 2540, Perrigo Pharmaceuticals holds a current and valid "Pharmacy-Wholesale" license (License No. A4-0001254) from the Delaware Board of Pharmacy. On information and belief, Perrigo Pharmaceuticals develops and manufactures pharmaceutical products for the United States market and derives substantial revenue from the sale of such products to customers in Delaware.

23. On information and belief, Perrigo Pharmaceuticals, directly or in concert with related companies including Perrigo UK and Perrigo Co., is doing business in Delaware, including in this Judicial District by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware.

24. Upon information and belief, Perrigo Pharmaceuticals, directly or in concert with related companies including Perrigo UK and Perrigo Co., has engaged in substantial and/or continuous and systematic contacts with Delaware which satisfy due process and confer personal jurisdiction over Perrigo Pharmaceuticals in Delaware.

25. Further, Perrigo Pharmaceuticals has committed, or aided, abetted, contributed to and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Meda and Cipla, which manufactures DYMISTA® for sale and use throughout the United States, including in this Judicial District. In addition, on information and belief, if Perrigo's ANDA received approval, Perrigo Pharmaceuticals would market and sell generic versions of DYMISTA® in Delaware.

26. Perrigo Pharmaceuticals has also been sued in this Judicial District and has previously consented to personal jurisdiction. *See, e.g.*, *Teva Branded Pharmaceutical Products R&D, Inc., et al v. Perrigo Pharmaceuticals Co., et al*, No. 12-cv-01101 (D. Del).

27. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b).

28. Plaintiffs are currently litigating the '620 and '428 patents in this Judicial District in litigation concerning generic versions of DYMISTA®. *See Meda Pharmaceuticals Inc. et al. v. Apotex Inc. et al.,* C.A. No. 14-cv-01453-LPS (D. Del.) and *Meda Pharmaceuticals Inc. et al. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 15-cv-00785-LPS (D. Del.).

REGULATORY REQUIREMENTS FOR APPROVAL OF NEW AND GENERIC DRUGS

29. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules FDA follows when considering whether to approve the marketing of pharmaceutical drugs.

30. With the passage of the Hatch-Waxman Act in 1984, the FFDCA provisions with respect to the generic drug approval process were amended in several aspects. One provision requires innovator drug companies to submit patent information to FDA "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). FDA publishes the

submitted patent information in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book").

31. The Hatch-Waxman Act further amended the FFDCA to permit generic drug companies to gain approval of generic copies of innovator drugs (also called "reference drugs") by referencing studies performed by the innovator, without having to expend the same considerable investment in time and resources. Thus, generic drug companies are permitted to file what is referred to as an ANDA under 21 U.S.C. § 355(j). When filing an ANDA, generic drug companies are required to review the patent information that FDA lists in the Orange Book for the reference drug and make a statutory certification (commonly called "patent certification") with respect to the same.

32. One such certification is the Paragraph IV certification, by which the generic drug company seeks FDA approval to market its generic drug products prior to patent expiration by stating in its ANDA that the Orange Book-listed patents are purportedly "invalid or will not be infringed…" 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

ASSERTED PATENTS

33. On May 1, 2012, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,168,620, also titled "Combination of Azelastine and Steroids." The Orange Book shows that the '620 patent's term ends on February 24, 2026. A true and correct copy of the '620 patent is attached hereto as **Exhibit A**.

34. On February 16, 2016, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,259,428, titled "Combination of Azelastine and Fluticasone for Nasal Administration." The Orange Book shows that the '428 patent's term ends on June 13, 2023. A true and correct copy of the '428 patent is attached hereto as **Exhibit B**.

35. Plaintiff Cipla is the owner of the ’620 and ’428 patents.

36. The claims of the ’620 and ’428 patents are directed to an intranasal formulation of azelastine hydrochloride and fluticasone propionate or methods of using the same.

37. Plaintiff Meda is the exclusive licensee of the ’620 and ’428 patents in the United States, pursuant to an exclusive license agreement between Meda and Cipla, of the right to make, use, and sell certain pharmaceutical preparations containing azelastine hydrochloride and fluticasone propionate to treat seasonal allergic rhinitis. Pursuant to that exclusive license, Meda currently markets an azelastine hydrochloride and fluticasone propionate combination nasal spray in the United States under the trademark DYMISTA®. The DYMISTA® product and the conditions of use for which DYMISTA® is approved fall within the claims of the ’620 and ’428 patents.

38. As exclusive licensee, Meda has the right to enforce the ’620 and ’428 patents.

MEDA’S APPROVED DRUG PRODUCT: DYMISTA®

39. Meda holds NDA No. 202236, which covers the DYMISTA® (137 mcg azelastine hydrochloride and 50 mcg fluticasone propionate) nasal spray. The FDA approved NDA No. 202236 on May 1, 2012, allowing Meda to market DYMISTA® throughout the United States for the relief of symptoms of seasonal allergic rhinitis (“SAR”).

40. The FDA lists the ’620 and ’428 patents in the Orange Book in connection with NDA No. 202236 because each individually claims the drug composition or methods for using the approved drug product. 21 U.S.C. § 355(b)(1).

PERRIGO’S ANDA

41. By Notice Letter dated July 28, 2016, Perrigo UK notified Meda and Cipla that it had submitted or caused to be submitted the Perrigo ANDA and a Paragraph IV certification

under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for a Generic Product purportedly bioequivalent to Meda's DYMISTA® product.

42. The Notice Letter states that Perrigo seeks approval from the FDA to engage in the commercial manufacture, use, and sale of the Generic Product before the expiration of the '620 and '428 patents.

43. The active ingredient in Perrigo's Generic Product is azelastine hydrochloride and fluticasone propionate.

44. By filing the Perrigo ANDA, Perrigo has necessarily represented to the FDA that its Generic Product has the same active ingredients as Meda's DYMISTA®, is bioequivalent to DYMISTA®, and is in the same dosage form (nasal spray) and strength (a combination of 137 mcg azelastine hydrochloride and 50 mcg fluticasone propionate) as DYMISTA®.

45. Further, pursuant to 21 CFR § 320.22 and FDA Guidance for Industry: Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products (July 2002), nasal spray products like Perrigo's Generic Product must be qualitatively and quantitatively (Q1/Q2) the same as the reference list drug, here Plaintiff Meda's DYMISTA®.

46. In its Notice Letter, Perrigo asserts that the '620 and '428 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of the Perrigo ANDA Product.

47. In its Notice Letter, Perrigo does not contest infringement of claims 1-18, 21, 22, 24-26, 28, 29, 31, 33, and 35-47 of the '620 patent which are directed to pharmaceutical formulations comprising azelastine and fluticasone.

48. In its Notice Letter, Perrigo does not contest that Perrigo's ANDA Product meets all of the limitations of claims 1-30 of the '428 patent.

49. The purpose of the Perrigo ANDA was to obtain approval under the FFDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Products with their proposed labeling prior to the expiration of the '620 and '428 patents.

50. Perrigo has knowledge of the claims of the '620 and '428 patents. Notwithstanding this knowledge, Perrigo has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Products with their proposed labeling immediately and imminently upon approval of the Perrigo ANDA. On information and belief, by such activities, Perrigo specifically intends infringement of the '620 and '428 patents.

51. On information and belief, Perrigo plans and intends to, and will, actively induce infringement of the '620 and '428 patents when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

52. On information and belief, Perrigo knows that its ANDA Products are especially made or adapted for a use that infringes the '620 and '428 patents, and that Perrigo's ANDA Products are not suitable for substantial noninfringing use. On information and belief, Perrigo plans and intends to, and will, contribute to infringement of the '620 and '428 patents immediately and imminently upon approval of the Perrigo ANDA.

53. The product and the conditions of use for which Perrigo seeks approval in its ANDA fall within one or more of the claims of the '620 and '428 patents. If approved, the importation, manufacture, sale, offer for sale and/or use of Perrigo's Generic Product would infringe one or more claims of the '620 and '428 patents. The filing of the Perrigo ANDA evidences Perrigo's intent to compete with Meda and place Perrigo's Generic Product into the State of Delaware where Meda's DYMISTA® product is currently sold.

54. An actual case or controversy exists between Plaintiffs and Perrigo with respect to infringement of each of the ’620 and ’428 patents.

55. This Complaint is being filed within 45 days from the date Meda and Cipla received the Notice Letter. 35 U.S.C. § 355(j)(5)(B)(iii).

COUNT I: INFRINGEMENT OF THE ’620 PATENT

56. Meda and Cipla reallege paragraphs 1 to 55 above as if fully set forth herein.

57. Perrigo’s submission of its ANDA infringes claims 1-13, 15-18, 21, 22, 24-26, 28, 29, 31, 33, and 35-47 of the ’620 patent under 35 U.S.C. § 271(e)(2)(A).

58. On information and belief, if the FDA approves Perrigo’s ANDA, Perrigo will further infringe claims 1-13, 15-18, 21, 22, 24-26, 28, 29, 31, 33, and 35-47 of the ’620 patent by making, using, offering to sell, and selling its Generic Product in the United States and/or importing such sprays into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

59. If Perrigo’s marketing and sale of its Generic Product before the expiration of the ’620 patent is not enjoined, Meda and Cipla will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’620 PATENT

60. Meda and Cipla reallege paragraphs 1 to 59 above as if fully set forth herein.

61. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

62. There is an actual case and controversy between Meda and Cipla on the one side, and Perrigo on the other, creating a justiciable case and controversy for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

63. Perrigo has made, and will continue to make, substantial preparations in the United States, including Delaware, to manufacture, sell, offer to sell and/or import the Generic Products.

64. Perrigo's actions indicate a refusal to change the course of its action in the face of acts by Meda and Cipla.

65. Any commercial manufacture, use, offer for sale, sale and/or importation of the Generic Products prior to patent expiry will constitute direct and/or contributory and/or active inducement of claims 1-13, 15-18, 21, 22, 24-26, 28, 29, 31, 33, and 35-47 of the '620 patent.

66. Unless Perrigo is enjoined from infringing, inducing infringement and contributing to the infringement of, the '620 patent, Meda and Cipla will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT III: INFRINGEMENT OF THE '428 PATENT

67. Meda and Cipla reallege paragraphs 1 to 66 above as if fully set forth herein.

68. Perrigo's submission of its ANDA infringes all claims of the '428 patent under 35 U.S.C. § 271(e)(2)(A).

69. On information and belief, if the FDA approves Perrigo's ANDA , Perrigo will further infringe all claims of the '428 patent by making, using, offering to sell, and selling its Generic Product in the United States and/or importing such sprays into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

70. If Perrigo's marketing and sale of its Generic Product before the expiration of the '428 patent is not enjoined, Meda and Cipla will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '428 PATENT

71. Meda and Cipla reallege paragraphs 1 to 70 above as if fully set forth herein.

72. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

73. There is an actual case and controversy between Meda and Cipla on the one side, and Perrigo on the other, creating a justiciable case and controversy for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

74. Perrigo has made, and will continue to make, substantial preparations in the United States, including Delaware, to manufacture, sell, offer to sell and/or import the Generic Products.

75. Perrigo's actions indicate a refusal to change the course of its action in the face of acts by Meda and Cipla.

76. Any commercial manufacture, use, offer for sale, sale and/or importation of the Generic Products prior to patent expiry will constitute direct and/or contributory and/or active inducement of all claims of the '428 patent.

77. Unless Perrigo is enjoined from infringing, inducing infringement and contributing to the infringement of, the '428 patent, Meda and Cipla will suffer substantial and irreparable harm for which there is no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Meda and Cipla respectfully request that this Court grant the following relief:

A. A judgment that Perrigo has infringed valid and enforceable claims of the '620 and '428 patents under 35 U.S.C. § 271(e)(2)(A);

B. A judgment and order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Perrigo's ANDA not be earlier than the latest of the expiration dates of the '620 and '428 patents, inclusive of any extension(s) and additional period(s) of exclusivity;

C. A judgment declaring that Perrigo's manufacture, use, sale, offer for sale, or importation into the United States of the Generic Product for which approval is sought in Perrigo's ANDA would constitute infringement of the '620 and '428 patents, or would induce or contribute to such infringement, pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

D. A permanent injunction enjoining Perrigo and its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, or offering to sell in the United States, or importing into the United States, the Generic Product for which approval is sought in Perrigo's ANDA , or any generic azelastine hydrochloride and fluticasone propionate combination nasal spray product that infringes or induces or contributes to the infringement of the '620 and '428 patents, until expiration of those patents;

E. A declaration under 28 U.S.C. § 2201 that if Perrigo, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Generic Products prior to patent expiry, it will constitute an act of direct and/or indirect infringement of the '620 and '428 patents;

F. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

G. An award of costs and expenses in this action; and

H. Such further and other relief as this Court determines to be just and proper.

ASHBY & GEDDES

/s/ Andrew C. Mayo

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